

K964076

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
LASERSCOPE ERBIUM:YAG LASER SYSTEM AND ACCESSORIES**

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**REGULATORY AUTHORITY:**

Safe Medical Devices Act of 1990, 21 CFR 807.92

JAN 8 1997

**COMPANY NAME/CONTACT:**

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**DEVICE TRADE NAME:**

Laserscope Erbium:YAG Laser System and Accessories

**DEVICE COMMON NAME:**

Erbium:YAG Laser System

**DEVICE DESCRIPTION:**

The Laserscope Erbium:YAG Laser System and Accessories consists of a moveable console containing power supplies, aiming and treatment lasers on a solid optical deck and a cooling mechanism to dissipate the heat generated by the system. A softouch keypad control panel with LCD displays enables the user to control the laser system operating parameters. The aiming beam is coincident with the Erbium:YAG beam and passes through an articulating arm. The aiming beam emerges at the distal end of a handpiece. Focusing handpiece adapters, which attach to the handpiece, are available in spot sizes of 1 - 5 mm.

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**DEVICE CLASSIFICATION:**

Erbium:YAG Laser Systems and Accessories have not been specifically classified; however Nd:YAG, CO<sub>2</sub>, and Argon Surgical Lasers have been classified as Class II medical devices by the OB/GYN, General, Plastic Surgery and ENT Device Advisory Panels.

**PERFORMANCE STANDARDS:**

All Laserscope Erbium:YAG Surgical Laser Systems and Accessories conform with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

**INDICATION FOR USE STATEMENT:**

The Laserscope Erbium:YAG Laser System and Accessories are indicated for use in procedures involving cutting (incision/excision), vaporizing and coagulating soft tissue.

All soft tissue is included such as skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

**Clinical Applications:**

Dermatology/Plastic Surgery  
General Surgery (Soft Tissue)  
Genitourinary  
Gynecology  
ENT Soft Tissue Procedures  
Oral and Maxillofacial Surgery  
Ophthalmology  
Podiatry

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**COMPARISON WITH PREDICATE DEVICE:**

The Laserscope Erbium:YAG Laser System and Accessories is substantially equivalent to the SEO Medical Trilase 2490.

The risks and benefits for the Laserscope Erbium:YAG Laser System and Accessories are comparable to the predicate device when used for similar clinical applications.

Since the Laserscope Erbium:YAG Laser System and Accessories are substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device, we believe it clearly meets the requirements for substantial equivalence according to Section 510(k) guidelines. Safety and effectiveness are reasonably assured, therefore justifying 510(k) clearance for commercial sale.